



## GUIDANCE FOR REGISTERED HEARING AID DISPENSERS ON OVER-THE-COUNTER HEARING AIDS

### Introduction to Over-The-Counter Hearing Aids

On August 17, 2022, the U.S. Food and Drug Administration (“FDA”) published a final rule adopting, in part, a new category of hearing aids for over-the-counter (“OTC”) sales. To read the final published rule, please use the following link to visit the [Federal Register](#). The final OTC rule went into effect on October 17, 2022.

**The information offered below should not be used in lieu of seeking appropriate legal advice and is not intended to answer general questions from registered dispensers regarding hearing aids. This guidance is subject to change and licensed professionals should frequently visit the Department’s website for important updates based on future interpretations of the regulation by the courts.**

### What are OTC hearing aids?

OTC hearing aids are hearing aids specifically approved by the FDA to be marketed and sold directly to customers without intervention by a hearing health professional.

### Who are OTC hearing aids for?

OTC hearing aids have been approved by the FDA and are approved for consumers with perceived mild to moderate hearing impairment. **They are not intended to be used by consumers with greater than moderate hearing loss or persons under 18 years of age.**

### Can registered hearing aid dispensers sell OTC hearing aids?

Yes, OTC hearing aids can be sold by registered hearing aid dispensers who are also dispensing “prescription” hearing aids.

### Can retailers sell both OTC hearing aids traditional (i.e., “prescription”) hearing aids?

OTC hearing aids can be sold by any consumer retailer, however, a registration is still required to dispense traditional (i.e., “prescription”) hearing aids.

### Who can dispense “prescription” hearing aids?

The FDA regulations did not change who can dispense “prescription” devices in New York. Accordingly, “prescription” devices can still be dispensed by a NYS registered hearing aid dispenser, a NYS licensed physician, a NYS licensed otolaryngologist, or a licensed audiologist registered as a hearing aid dispenser. Physicians and



otolaryngologists who conduct the evaluation may not dispense hearing aids for a profit to the patient that received the medical evaluation.

#### How are OTC hearing aids distinguished from “prescription” devices?

There are many technical differences between these devices, however, a readily available way to distinguish between these types of devices is to examine the labeling. OTC hearing aids are required to comply with specific FDA labeling requirements, including but not limited to, containing the following warning:

**WARNING: If you are younger than 18, do not use this.**

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

21 CFR § 800.30(c).

#### As a registered dispenser, do the same sale policies apply to OTC hearing aids as are applicable to “prescription” hearing aids?

No, the same sale policies do not apply. Dispensers selling “prescription” devices must still comply with pre-existing rules, including but not limited to, direct observation of the consumer’s ear canals, fitting, and testing. OTC hearing aids can be sold, by a registered dispenser, without satisfying the pre-existing requirements. A registered dispenser may sell **OTC hearing aids** over the phone, internet, mail, in-person transactions, or by other commercially available means.

#### As a registered dispenser, do the same return policies apply to OTC hearing aids as are applicable to “prescription” hearing aids?

No, the same return policies do not apply. Dispensers selling “prescription” devices must still comply with pre-existing rules, including but not limited to, the minimum 45-day return policy. See, NY General Business Law § 798(11)(h). Dispensers that sell OTC hearing aids must establish a return policy consistent with NY General Business Law § 218-a. For general information about refunds of consumer products, please visit the [Department’s Division of Consumer Protection](#).

#### Are Personal Sound Amplification Products (“PSAPs”) the same as OTC hearing aids?

No, the FDA has classified PSAPs in a different category from OTC hearing aids. PSAPs are not regulated as “hearing aids”.

#### If I have more questions, where can I get help?

If you have questions regarding OTC devices, please contact the FDA at 888-INFO-FDA.

